

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Art Unit	: 1616	Customer No. 035811
Examiner	: Ernst V. Arnold	
Serial No.	: 10/722,737	Docket No.: BSG 021 US
Filed	: November 25, 2003	(END-09-1164R)
Inventors	: Bradley S. Galer	
	: Arnold R. Gammaitoni	Confirmation No.: 7300
	: Robert H. Dworkin	
Title	: COMPOSITIONS AND METHODS	
	: FOR TREATING NEUROPATHIC	
	: SENSORY LOSS	

Dated: October 15, 2010

REPLY BRIEF

Mail Stop Appeal Brief - Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

This is submitted in response to the Examiner's Answer dated August 17, 2010.

The Appellants respond to the rejections for anticipation and obviousness in this Reply Brief.

The Rejection of Claims 1-11 as anticipated by Hind as evidenced by Medline Plus and Rowbotham

The Appellants respectfully maintain the Examiner has not met the burden of showing inherency. It is well established that the burden of proving inherency rests on the PTO and that burden requires the PTO to demonstrate that each and every element of the claims is necessarily present in the prior art. As discussed in the Appeal Brief, the burden requires a showing that the alleged inherent element is "necessarily present" and "would be so recognized by one of skill in the art." *Continental Can Co. USA v. Monstanto Co.*, 948 F.2d 1264 (Fed. Cir. 1991). The PTO must also point to "a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art." *See Ex Parte Levy*, 17 USPTO 2d 1461 (Bd. Pat. App. & Inter. 1990). Inherency may not be

established by probabilities or possibilities and the mere fact that a certain thing may result from a given set of circumstances is not sufficient. *In re Robertson*, 169 F.3d 743, 745 (Fed. Cir. 1999).

The burden in this application is that of demonstrating that numbness or negative sensory phenomena are necessarily present in cases of post-herpetic neuralgia and that treatment of the post herpetic neuralgia according to the methods of Hind necessarily results in the treatment of that numbness claimed.

The Examiner's Answer states that "simply by identifying a patient with post herpetic neuralgia, where one of the symptoms is numbness, then numbness is also inherently identified and treated by application of lidocaine to decrease the numbness in the patient. It is simply inherent in the method of Hind." However, this is just unsupported speculation. The Examiner has failed to indentify any individual patient having a concurrence of neuropathically-induced negative sensory phenomena or numbness and post-herpetic neuralgia that was treated with a lidocaine patch disclosed in Hind, let alone demonstrate that every PHN patient necessarily experiences numbness with the neuralgia. The rejection's reliance on a reference to an unspecified number of post-herpetic neuralgia patients with deficits in the perception, and its assumption that treatment of any patient with post-herpetic neuralgia with a lidocaine patch, is insufficient to meet the burden of showing inherency. The rejection and the Answer rely on the mere possibility that a post-herpetic neuralgia patient both always suffers from numbness and may have been treated with a lidocaine patch to show inherency. However, a rejection based on inherency cannot rely on mere possibility or probability that a post-herpetic neuralgia patient necessarily experienced the symptom of numbness and was treated with the lidocaine patch of Hind. *See, In re Robertson, supra*.

In asserting that "simply...identifying a patient with post herpetic neuralgia" is enough, the Examiner's arguments improperly attempt to shift the initial burden to the Appellants to show that it is physically impossible for a patient to experience both post-herpetic neuralgia and numbness or negative sensory phenomena. For example, page 10 of the Examiner's Answer erroneously concludes that "a teaching where negative sensory phenomena are present and co-extensive with the pain...meets the limitations of the instant claims because this patient population is not excluded by the instant claim language." Thus, to overcome the rejection, the Examiner demands that the Appellants demonstrate that not a single post-herpetic neuralgia patient has ever experienced any degree of numbness or negative sensory phenomena.

This, too, is an incorrect statement of the law. The Appellants are not required to demonstrate the impossibility of a certain population of neuralgia patients experiencing both pain and negative sensory phenomena, or even to rebut claims of a possibility or probability of such a concurrence. Instead, as discussed above, in basing an argument on inherency, the PTO is initially required to satisfy the burden of demonstrating that numbness or negative sensory phenomena are necessarily present in cases of post-herpetic neuralgia and that treatment of the post herpetic neuralgia according to the methods of Hind necessarily results in practice of each and every step of the claimed method.

The Appellants maintain that the PTO is required to identify a teaching in any of the cited documents that discloses, either expressly or inherently, each of the steps of the method recited in Claim 1. *See, Verdegall Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631 (Fed. Cir. 1987) ("A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference."(emphasis added)). The PTO has failed to make this showing.

The rejection and the Examiner's Answer conflates Hind's method of using a lidocaine patch to treat post-herpetic neuralgia with the methods of using a lidocaine patch to treat neuropathically-induced negative sensory phenomena or numbness as claimed. Specifically, at page 10, the Answer states that "treatment of one [i.e. pain] necessarily treats the other [i.e. treat neuropathically-induced negative sensory phenomena or numbness]." However, the rejected claims do not simply recite treatment of negative sensory phenomena with a lidocaine patch. Instead, the claims clearly recite the steps of "identifying a patient with neuropathically-induced negative sensory phenomena" and "identifying a locus of the neuropathically-induced negative sensory phenomena." The Appellants respectfully submit that the Answer's oversimplification of the claims fails to consider each and every element of the rejected claims, particularly with respect to these steps.

The application of a lidocaine patch to the locus of post-herpetic neuralgia as described by Hind neither inherently nor necessarily results in the practice of each of the claimed steps. For the sake of argument, the Appellants note that, even if a patient hypothetically suffered from both neuropathically-induced negative sensory phenomena and post herpetic neuralgia at the same locus, treatment of post herpetic neuralgia with a lidocaine patch does not necessarily require the steps of "identifying a patient with neuropathically-induced negative sensory phenomena" and "identifying a

locus of the neuropathically-induced negative sensory phenomena.” Indeed, a treatment provider seeking to treat post-herpetic neuralgia in this hypothetical patient with the method of Hind may be wholly ignorant as to the hypothetical concurrence of neuropathically-induced negative sensory phenomena and may apply a lidocaine patch simply to treat the neuralgia. In such a case where the treatment provider is not aware of all of the patient’s symptoms, or the patient is not manifesting the symptom of numbness, he or she could not possibly both “[identify] a patient with neuropathically-induced negative sensory phenomena” and “[identify] a locus of the neuropathically-induced negative sensory phenomena.” Consequently, the Appellants maintain that the method recited in the rejected claims does not “necessarily flow” from the practice of Hind and the PTO has not met the initial burden of showing that the rejected claims are inherently anticipated by the cited references.

The Appellants again respectfully request the reversal of the rejection of Claims 1-11 as anticipated by Hind as evidenced by Medline Plus and Rowbotham.

The Rejection of Claims 1-11 as Obvious over Hind in view of Wolicki as evidenced by Medline Plus and Rowbotham

The rejection concedes that Hind fails to disclose or teach various benzoic acid derivatives. The rejection relies on Wolicki to cure this deficiency. The rejection alleges that one of skill in the art would have been motivated to combine the benzoic acid derivatives taught by Wolicki.

The Appellants maintain that it would not be obvious to one skilled in the art to treat numbness or neurologically-induced negative sensory phenomena by topical application of an anesthetic or benzoic acid derivatives. The Appellants respectfully submit that the rejection improperly dismisses the unexpected results obtained from practice of the claimed method. As discussed in the Appeal Brief, the claimed methods achieve the counter-intuitive effect of treating numbness or negative sensory phenomena with the application an anesthetic, a pharmaceutical commonly used to induce numbness. In light of this counter-intuitive result and the failure of Hind or the other cited references to teach or suggest this method, the Appellants submit that the claimed methods are neither obvious nor “inherently obvious.” The disclosure of benzoic acid derivatives in Wolicki does not cure this deficiency.

The Appellants again respectfully request the reversal of the rejections of Claims 1-11 as obvious over Hind in view of Wolicki as evidenced by Medline Plus and Rowbotham.

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In light of the foregoing and the Appeal Brief, the Appellants respectfully submit that the rejections should be reversed and the solicited claims allowed.

Respectfully submitted,

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